

## **Methodological Note of Alcon Bulgaria EOOD**

**on Disclosure of Payments and other Transfers of Values to Health Care Professionals and Health Care Organizations following the 'EFPIA Code on Disclosure of Transfers of Value' and/or 'MedTech Europe Code of Ethical Business Practice'**

**Country:** Bulgaria

**Division:** Alcon

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## 1. Reference to National Transparency Laws and Regulations

Novartis supports laws and regulations that promote transparency around relationships between healthcare companies, Healthcare Professionals (HCPs) and Healthcare Organizations (HCOs) associated with Transfers of Value (ToVs)<sup>1</sup> related to prescription-only medicines by establishing a single, consistent transparency standard in Europe for disclosing ToVs across its divisions and European countries, by following the EFPIA transparency requirements and requirements set in local transparency laws.

As a Novartis Company, Alcon Bulgaria EOOD (“**Alcon Bulgaria**”) complies with the obligation to collect, disclose and report ToVs related to prescription-only medicines to HCPs/HCOs in accordance with the Code of ARPharM for Disclosure of Transfers of Value by Pharmaceutical Companies to Healthcare Professionals and Health Organizations (“**the ARPharM Disclosure Code**”), which implements the requirements of the EFPIA Code on Disclosure of Transfers of Value from Pharmaceutical Companies to Healthcare Professionals and Healthcare Organizations (“**the EFPIA Disclosure Code**”).

As country part of the European Economic Area agreement without a MedTech European National Association Alcon Bulgaria also complies with the obligation to collect, disclose and report ToVs related to educational grants to HCOs/PCOs (Professional Conference Organizer) in accordance with the MedTech Europe Code of Ethical Business Practice On Disclosure Of Transfers Of Value From Medical Device Companies To Healthcare Organization and Professional Conference Organizer.

## 2. Purpose of the Methodological Note

This document is intended to serve as supporting documentation for the 2018 Alcon Bulgaria Disclosure Report. Alcon Bulgaria’s position is based on the interpretation of the current version of the EFPIA Disclosure Code, MedTech Disclosure Code aligned with local transparency laws and the ARPharM Disclosure Code.

The Methodological Note summarizes the disclosure recognition methodologies and business decisions as well as country specific considerations applied by Alcon Bulgaria in order to identify, collect and report ToVs for each disclosure category as described in Section 3.01 of the EFPIA Disclosure Code and Chapter 4, Section 3 of the Medtech Disclosure Code.

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<sup>1</sup> A definition on the terms “HCP/HCO” and “ToVs” is provided in chapter 9 of this document.

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### **3. Novartis' Commitment and Responsibility for Disclosure**

Novartis supports laws and regulations that promote transparency around relationships between healthcare companies and HCPs/HCOs associated with ToVs related to prescription-only medicines and medical devices.

Novartis establishes a single, consistent transparency standard for disclosing ToVs in all EFPIA countries.

Moreover MedTech Europe created a single platform (EthicalMedTech website) for Member Companies to disclose ToVs in MedTech Europe geographic area<sup>2</sup>.

### **4. Scope of Alcon Bulgaria's Disclosure on Transfers of Value**

This 2018 Alcon Bulgaria Disclosure Report is following the disclosure standards pursuant to the ARPharM Disclosure Code and MedTech Disclosure Code. Subject to this disclosure report are all direct or indirect ToVs related to prescription-only medicines and medical devices disclosed by Alcon Bulgaria to or for the benefit of a Recipient made by any Novartis affiliate as described in Article 3 of the EFPIA Disclosure Code and ToVs for educational grants described in Chapter 4, Section 3 of the MedTech Disclosure code. Further details on the disclosure scope will be provided in chapter 4 of this document.

The legal definition of 'prescription-only medicine' is pursuant to the Medicinal Products in the Human Medicines Act. ToVs related to a group of products that includes prescription-only medicines (e.g. combination products/diagnostics and medicinal products) are reported in total following the disclosure requirements of the EFPIA Disclosure Code.

In summary:

- The 2018 Alcon Bulgaria Disclosure Report covers direct and indirect ToVs, payments, in kind or otherwise, made to HCPs/HCOs in connection with the development and sale of prescription-only medicinal products exclusively for human use, whether for promotional purposes or otherwise.
- The 2018 Alcon Bulgaria Disclosure Report covers provision of funds for the support and the advancement of genuine medical education of HCP, patients and/or the public on clinical, scientific and/or health care topics relevant to the therapeutic areas as educational grants.

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<sup>2</sup> The MedTech Europe Geographic Area includes the countries in the European Economic Area as well as those countries where Member Associations are located.

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In this/these reports, Alcon Bulgaria discloses the amounts of value transferred by type of ToVs with data coverage from January 1<sup>st</sup> 2018 to December 31<sup>st</sup> 2018. Alcon disclosure is performed for the full calendar year 2018.

4.4. Whenever possible, Alcon follows the principle of disclosure on individual HCP/HCO level, to ensure that each Recipient is referred to in such a way that there is no doubt as to the identity of the HCP/HCO benefitting from the ToVs. Aggregate disclosure for non Research and Development ToVs is only used in exceptional cases, e.g. if consent could not be obtained despite best efforts or in case of withdrawal of consent.

With regards to the Novartis portfolio transition Alcon ophthalmic pharmaceuticals business to move to Pharmaceuticals Division the following is applicable: the entity paying for the engagement of the HCP reports the relevant ToV.

## **5. Alcon's Disclosure Recognition Methodology and Related Business Decisions**

This chapter represents the central pillar of this Methodological Note. It provides comprehensive information on the terminology definitions, recognition methodology and business decisions that affected how the published ToVs data was established for each category of the disclosure report.

### **5.1 Definition of Direct and Indirect Transfer of Values**

Alcon Bulgaria applies the EFPIA definition of ToVs as outlined in EFPIA Disclosure Code schedule 1.01 - pursuant to the definition under Article 4 of the ARPHARM Disclosure Code.

According to the EFPIA Disclosure Code schedule 1, the following definitions apply throughout this report:

- Direct ToVs are defined as those ToVs, payments or in kind, made directly by the Novartis affiliate to the benefitting HCPs/HCOs.
- Indirect ToVs are defined as those ToVs made through an intermediary (third party) on behalf of a Novartis affiliate for the benefit of HCP/HCO where the Novartis affiliate knows or can identify the HCP/HCO that benefits from the ToVs.

In general, ToVs are reported at the level of the first identifiable Recipient which falls under the EFPIA definition of an HCP/HCO. To the extent possible, disclosure is made under the name of the individual HCP or at the HCO level, as long as this could be achieved with accuracy, consistency and compliance with the EFPIA Disclosure Code and pursuant to the definition under Article 4 of the ARPHARM Disclosure Code. Where a ToV was made to an individual HCP rendering services on behalf of an HCO indirectly via this HCO, such ToVs are only disclosed once on either Recipient level.

ToVs from distributors of Alcon Bulgaria to HCPs/HCOs whose primary practice is in an EFPIA country must be disclosed if the distributor is making a ToV on behalf of Alcon Bulgaria (influencing the promotional activities and selection of Recipient). ToVs to HCPs/HCOs made through a Continuous Medical Education (CME) non-HCO provider are disclosable if the 3rd party CME provider is acting on behalf of Alcon Bulgaria (and Alcon Bulgaria influenced choice of HCPs/Faculty).

According to the MedTech Europe Code of Ethical Business Practice Part 1, Section 6 the following definition applies:

- Member Companies may provide financial and/or in kind support (e.g. Member Company products) to Third Party Organised Educational Events in accordance with the rules of this Code.

## 5.2 Definition of Cross-border Transfer of Values

Alcon Bulgaria applies the EFPIA definition of cross-border ToVs as being a Transfer of Value to an HCP/HCO that **occurred outside** the country where the Recipient has its primary practice, principal professional address or place of incorporation provided that this country is an EFPIA and MedTech regulated countries.

In general, such ToVs are disclosed in the country where the Recipient has its principal practice, principal professional address or place of incorporation. .

## 5.3 Transfer of Value Categories According to the EFPIA Disclosure

Alcon Bulgaria applies the EFPIA definition of the ToVs categories as outlined in EFPIA Disclosure Code Article 3.01 - pursuant to Article 4 of the ARPHARM Disclosure Code.

The following categories constitute the EFPIA Disclosure Template for the 2018 Alcon Bulgaria Disclosure Report:

- Donations and grants to an HCO
- Contribution to costs related to events to an HCO/HCP, such as:
  - Sponsorship agreements
  - Registration fees
  - Travel and accommodation
- Fees for service and consultancy to an HCO/HCP
  - Fees for service and consultancy
  - Expenses related to fees for service and consultancy
- Research and development

Details on the recognition methodology and business decisions affecting how the published ToVs data was constructed for each category can be found in the subsequent sub-chapters.

### 5.3.1 Transfer of Values Related to Donations and Grants

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Alcon Bulgaria applies the EFPIA definition of the “Donations and Grants” category as outlined in EFPIA Disclosure Code Article 3.01 – pursuant to § 1, p. 1 of Chapter VI of the ARPHARM Disclosure Code in relation to Article 11 of the ARPharM Code of Ethics.

Grants to a hospital/university department or teaching institution are disclosed in the name of the legal entity that is the Recipient of the ToVs – this may be the hospital, university or independent department within these organizations.

ToVs to a charitable organization are disclosed under the “Donations and Grants” category in the name of the benefitting HCO if the charitable organization falls under the EFPIA definition of a benefitting HCO. Charitable product donations made to HCOs in the context of humanitarian aid are also disclosed in the “Donations and Grants” category.

When grant requests from HCOs include explicit support for publication, then these ToVs are disclosed in the “Donations and Grants” category.

### **5.3.2 Transfer of Values Related to Contribution to Costs of Events**

Events are defined as promotional, scientific or professional meetings, congresses, conferences, symposia, and other similar events (including but not limited to advisory board meetings, visits to research or manufacturing facilities, and planning, training or conducting of investigator meetings for clinical trials and non-interventional studies) organized or sponsored by or on behalf of Alcon Bulgaria pursuant to Schedule 1 of the EFPIA Disclosure Code.

ToVs to participating HCPs/HCOs related to such events falling under the definition above are disclosed in the “Costs of Events” sub-categories “Sponsorship Agreements”, “Registration Fees” or “Travel and Accommodation”. ToVs that by exception fall into the “Fees for Service and Consultancy” or “Research and Development” categories are outlined in the respective chapters 5.3.3 and 5.3.4.

#### **5.3.2.1 Transfer of Values Related to Contribution to Costs of Events – Sponsorship Agreements**

Alcon Bulgaria applies the EFPIA definition of the “Sponsorship Agreements” category as outlined in EFPIA Disclosure Code Article 3.01, following the principle that “Sponsorship Agreements” are formalized in contracts that describe the purpose of the sponsorship and the related direct or indirect ToV – pursuant to Chapter III and § 1q p.1 of Chapter VI of the ARPharM Disclosure Code in relation to Article 11 of the ARPharM Code of Ethics.

In general, indirect sponsorship of an HCP through an HCO is disclosed under the “Sponsorship Agreements” category as payment to the HCO as first level Recipient of the ToV. This applies to the following categories: ToVs related to intermediaries selecting the faculty who acted as speakers or faculty at an event; ToVs related to advertising space, sponsoring of speakers/faculty, satellite symposia at congresses, courses provided by HCOs.

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ToVs made through a professional conference organizer (PCO) as intermediary e.g. for the hire of booths or stand space on behalf of an HCO, are disclosed as ToVs either in the “Sponsorship Agreements” category or as “Fees for Services and Consultancy” – depending on the nature of the spend, in the name of the sponsored HCO as benefitting Recipient.

If the contract requires the HCOs to use some of the amount to invite a number of HCPs selected by Alcon Bulgaria to an event, the ToV is split and disclosed based on the ToVs category the amount was used for (“sponsoring agreements” of speakers/faculty; “registration fees” or “travel and accommodation”) individually in the name of each HCP.

If an intermediary organized an event with sponsorship of Alcon Bulgaria on behalf of more than one HCO, the ToV is disclosed based on the actual ToV allocated to each benefitting HCO wherever possible. In cases where it was not possible to accurately allocate the ToVs to each HCO involved in the event, it was assumed that all HCOs had similar levels of involvement. In consequence, the ToV was divided by the number of HCOs, which would each be reported as having received their equal share of the ToVs.

Alcon Bulgaria discloses ToVs related to preceptorships considering that such non-promotional independent “practical” training offered to HCPs by other HCPs or HCOs – typically in a specific disease area at a reputed teaching institution (faculty of medicine, university, university hospital) – falls under the definition of “Events” and is disclosed in the name of that contracting entity.

#### 5.3.2.2 Transfer of Values Related to Contribution to Costs of Events – Registration Fees

Alcon Bulgaria applies the EFPIA definition of the “Registration Fees” related to cost of events categories as outlined in EFPIA Disclosure Code Article 3.01 – pursuant to Article 18, p. 1.2.1 and p. 2.1.1 of the ARPharM Disclosure Code.

In general (and for all types of events), whenever registration fees were charged for an event organized or sponsored by or on behalf of Alcon Bulgaria, they are disclosed in the name of the benefitting HCP or HCO. The total amount of registration fees paid in a given year to a HCO should be disclosed on an individual basis (in the name of the HCO) under “Contribution to Costs of Events”. The total amount of Registration Fees paid in a given year to a HCP who is the clearly identifiable Recipient is disclosed on an individual basis (in his/her name) under “Contribution to Costs of Events”.

ToVs related to virtual congresses (e-congresses) are reported as actual spend. Aggregate spend is disclosed under the HCO in each country and is reported in “Registration Fees” category.

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### 5.3.2.3 Transfer of Values Related to Contribution to Costs of Events – Travel & Accommodation

Alcon applies the EFPIA definition of the “Travel and Accommodation” related to cost of events categories - pursuant to Article 18, p. 1.2.3 and p. 2.1.2 of the ARPharM Disclosure Code.

ToVs covered under the “Travel and Accommodation” category include costs of transportation (e.g. flights, trains, buses, taxis, etc., car hire tolls, parking fees) and accommodation (e.g. hotel, apartment, etc.).

In general, ToVs related to travel and accommodation are disclosed at first level Recipient basis. If the ToVs are made through an HCO or intermediary (third party), it will be disclosed at individual HCP level whenever possible (see chapter 5.1).

ToVs related to travel and accommodation for a group of HCPs such as group transportation by bus are disclosed on an aggregate basis. If the mass transportation is shared by a group of HCPs who have their primary practice in different countries, the ToVs are disclosed in aggregate with the total cost divided equally among the planned number of benefitting HCPs per country.

In case the benefitting HCP partly bears the costs related to travel and accommodation, the net amount of the Alcon Bulgaria payment offset by payment from HCP is disclosed as ToV under the “Travel and Accommodation” category in the name of the HCP.

### 5.3.3 Transfer of Values Related to Contribution to Fees for Service and Consultancy

#### 5.3.3.1 Transfer of Values related to Contribution to Fees for Service and Consultancy – Fees

Alcon Bulgaria applies the EFPIA definition of the “Fees for Service and Consultancy” category as outlined in EFPIA Disclosure Code Article 3.01 - pursuant to Article 18, p. 1.3 and p. 2.2 of the ARPharM Disclosure Code.

ToVs covered under the “Fees for Service and Consultancy” category, whether made directly or through a third party to an HCP/HCO, include but are not limited to services performed in connection with third-party congresses, speakers’ fees, speakers’ trainings, medical writing, data analysis, development of education material, interviews e.g. on Alcon products or research, general consulting/advising, services by distributors, consultancy for tool/questionnaire selection or analysis.

Alcon Bulgaria has formalized such collaboration in a contract describing the purpose of ToVs. In general, the ToVs received by the contracting entity – which may be an HCP, a legal entity owned by an HCP (considered an HCO under the EFPIA Disclosure Code) or an HCO – are disclosed under the “Fees for Service and Consultancy” category in the name of that contracting entity.

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ToVs related to market research studies for which the identity of the Recipient was known to Alcon Bulgaria, are disclosed under the “Fees for Service and Consultancy” category. ToVs related to market research studies for which the identity of the HCP/HCO was not known to Alcon Bulgaria are not disclosed as the right of the respondents to remain anonymous is embodied in market research definitions and relevant codes of conduct worldwide.

ToVs related to medical writing and editorial support made directly or indirectly to an HCO/HCP are disclosed either under the “Fees for Service and Consultancy” in the name of the benefitting HCP/HCO or under the “Research and Development” category in aggregate form – pursuant to Article 21 of ARPharm Disclosure Code. The following instances of medical writing and editorial support are covered under the “Fees for Service and Consultancy” category: case studies, congress write ups, article and abstracts, manuscripts, poster, clinical management guideline, supplements. ToVs related to the following Research and Development related activities (see chapter 5.3.4) but when they do not fall under the definition of Research and Development ToVs as stated by the EFPIA Disclosure Code and EFPIA HCP Code Article 15 are disclosed under the “Fees for Services and Consultancy” category in the name of the benefitting Recipient, for example:

- Retrospective non-interventional studies not falling under the definition of Research and Development ToVs as per EFPIA Disclosure Code definition of Research and Development Schedule 1 and EFPIA HCP Code Article 15
- Investigator initiated trials, investigator sponsored trials and Investigator meeting, in the exceptional case when such ToV do not fall under the definition of Research and Development mentioned above
- Activities contracted to Contract Research Organizations (CROs) where Alcon Bulgaria makes indirect ToVs to HCPs/HCOs but not falling under the EFPIA Research and Development definition
- Project activities related to e.g. disease area, mode of action, market placement, adjudication committees, speaker programs, scientific meetings, ethics committees, steering committee and advisory board activities not in scope of the EFPIA Research and Development definition
- ToVs related to consultancy for tool/questionnaire selection or analysis and reporting of results not in scope of the EFPIA Research and Development definition

#### 5.3.3.2 Transfer of Values related to Contribution to Fees for Service and Consultancy – Related Expenses

Alcon Bulgaria fully complies with the EFPIA definition of the “Fees for Service and Consultancy - Related Expenses” category as outlined in EFPIA Disclosure Code Article 3.01 - pursuant to Article 18, p. 1.3 and p. 2.2 of the ARPHARM Disclosure Code.

In general, the ToVs amount related to expenses such as travel and accommodation cost associated with the activity agreed to in a “Fees for Service” or “Consultancy” contract do not constitute part of the fees itself; in consequence such ToVs are disclosed under the “Related Expenses” category in the name of the benefitting HCP/HCO.

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In case such expenses were not material (e.g. of limited value), or when such expenses despite best effort could not be accurately disaggregated from the fees, such ToVs have been disclosed as part of the total amount of fees under the “Fees for Service or Consultancy” category.

### 5.3.4 Transfer of Values Related to Research and Development

Alcon Bulgaria applies the EFPIA definition of the “Research and Development” category as outlined in EFPIA Disclosure Code – Schedule 1, the definition of non-clinical studies in the OECD Principles on Good Laboratory Practice, the definition of clinical trials and non-interventional studies (as defined in Directive 2001/20/EC and 15.01 of the EFPIA HCP Code), pursuant to Section 5 and Section 21 of the ARPHARM Disclosure Code.

ToVs related to the following Research and Development activities are disclosed under the “Research and Development” category in aggregate form whenever they fall under the definition of Research and Development by the EFPIA Disclosure Code, for example:

- Activities related to the planning or conduct of non-clinical studies, clinical trials or prospective non-interventional studies and that involve the collection of patient data from or on behalf of individual, or groups of HCPs specifically for the study (Section 15.01 of the EFPIA HCP Code).
- IIT (Investigator initiated trials) and IST (Investigator sponsored trials - since, although not initiated by Alcon Bulgaria, they may benefit from Alcon Bulgaria.
- Post marketing trials, investigator meetings - in which case the total ToV amount is disclosed and in case of participating HCP from other countries, the total actual cost per meeting (incl. infrastructure, travel, logistic and with exclusion of meals whenever possible) is divided by the number of participants per country of practice
- Activities contracted to CROs, where Alcon Bulgaria makes indirect ToVs to HCPs/HCOs falling under the definition of Research and Development
- ToVs related to early stage research if falling under the definition of Research and Development in the EFPIA Disclosure Code

In case ToVs relating prospective and retrospective non-interventional studies cannot be distinguished, all non-interventional studies are disclosed on an individual basis.

ToVs made by or on behalf of Alcon Bulgaria **related to consultancy activities** are disclosed under the “**Research and Development**” category in aggregate form whenever they fall under the definition of Research and Development by the EFPIA Disclosure Code: consultancy activities related to the planning/conduct of non-clinical studies, clinical trial or prospective non-interventional studies, ethics committees, steering committee and advisory board activities related to the planning or conduct of non-clinical studies, clinical trial or prospective non-interventional studies, adjudication committees, speaker programs, scientific meetings.

ToVs related to **licensing fees** paid for the use of Clinical/Health Economics and Outcomes Research questionnaires and tools, if the questionnaires and tools are intended for use with

a Research and Development project/study are reported in aggregate form under the “Research and Development” category.

The following instances of medical writing and editorial support (as defined in chapter 5.3.3) are covered under the “Research and Development” category: investigator’s brochure (trials), clinical study report (trials), clinical report, safety report; generally all types of medical writing related to clinical trials or related to Research and Development activities.

In 2018 Alcon Bulgaria has not performed ToVs related to the following Research and Development.

## **5.4 Transfer of Value Categories According to the MedTech Disclosure Code**

Alcon Bulgaria applies the MedTech definition of the ToVs in the Definition of “Educational Grants” as outlined in the MedTech Disclosure Code in Part 1, Chapter 4, Section 3.

The following categories constitute the MedTech Disclosure template for the 2018 Alcon Bulgaria Disclosure Report:

- Educational grants to support Third Party Organised Events (including support for HCP participation at Third Party Educational Events)
- Other educational grants to HCOs (including scholarships, fellowships and/or grants for public awareness campaigns)

### **5.4.1 Transfer of Values Related to Educational Grants to support Third Party Organised Educational Events**

Alcon Bulgaria applies the MedTech definition of the “Educational Grants” category as outlined in MedTech Europe Code of Ethical Business Practice Part 1, Chapter 4, Section 3.a, following the general principle that any Third Party Organised Educational Event supported by way of an educational grant from a Member Company to a HCO must:

- Comply with Part 1, Chapter 1 “General Criteria for Events” of the MedTech Disclosure Code, and
- Where applicable, have approval via the Conference Vetting System (CVS) (<http://www.ethicalmedtech.eu/conference-vetting-system/>)

#### **5.4.1.1 Support for HCP Participation at Third Party Organised Educational Events**

Where the educational grant is provided for the purpose of supporting HCPs’ attendance at Third Party Organised Educational Events, the HCO receiving the grant shall be solely responsible for selection of participants and this shall be expressly reflected in the written grant agreement.

#### 5.4.1.2 Support for Third Party Organised Educational Events

Where the prospective beneficiary of an educational grant is the organizer of the Third Party Organised Educational Event and is also a HCO, the recipient HCO shall be solely responsible for:

- The programme content;
- The selection of faculty; and
- The payment of faculty honoraria, if any.

Member Companies shall not have any detailed involvement in determining the content of the educational programme for selection of faculty and this shall be reflected in the written grant agreement. If expressly requested to do so, Member Companies may recommend speakers or comment on the programme.

#### **5.4.2 Transfer of Values Related to Other Educational Grants to Healthcare Organizations**

Alcon Bulgaria applies the MedTech definition of the “Other Educational Grants” category as outlined in MedTech Europe Code of Ethical Business Practice Part 1, Chapter 4, Section 3.b and c, following the general principle for:

##### 5.4.2.1 Scholarships and Fellowships:

Member Companies may provide educational grant on a restricted basis in the form of grants for scholarships and fellowships to support advancement of genuine medical education of HCPs.

Only HCOs where HCPs are in training shall be eligible to request and/or receive such educational grants. A Member Company shall not provide educational grants to support scholarships and fellowships upon request of individual HCPs. Similarly, the Member Company shall not have any involvement in any way in the selection of the HCPs who will benefit from the educational grant and this shall be reflected in the written grant agreement between the Member Company and the recipient HCO.

##### 5.4.2.2 Grants for Public Awareness Campaigns:

Member Companies may also provide educational grants on a restricted basis to HCOs for the legitimate purpose of providing information, promoting awareness and/or educating patients, carers or the general public about relevant healthcare topics or medical conditions or diseases in therapeutic areas in which the Member Company is interested and/or involved.

## **6. Measures Taken to Ensure Compliance with Data Privacy Requirements**

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This chapter describes measures taken by Alcon Bulgaria to ensure compliance with data privacy regulations, rules on consent collection and managing of relevant information in compliance with relevant internal rules, data privacy laws and regulations.

## **6.1 Safeguarding Measures to Address Lawful Collection, Processing and Transfer of HCPs' Personal Data**

Data privacy refers to the individual's fundamental right to control the use of, access to and disclosure of information that describes or identifies the individual ("personal Information"). To fulfill the transparency disclosure requirements, it is necessary to collect, process and disclose such personal data within and outside of Alcon Bulgaria.

This data will be published for 3 years following the disclosure (disclosure has to be done not later than 6 months as of the end of the year of payment) and shall be stored by Alcon Bulgaria for a period of 5 years as of the end of the payment year. Alcon Bulgaria may carry out further processing of HCP Information, provided that this is permitted according to the applicable data protection law and/or by explicit consent by the respective HCP.

The disclosure of such personal information by Alcon Bulgaria is at all times limited to the intended purposes. We have implemented appropriate technical and organisational measures to provide an adequate level of security and confidentiality to your personal data.

In case personal data had to be transferred from countries to the central Novartis Transparency data repository manually (e.g. Excel) or via interfaces, applicable local regulations for the transfer were assessed at local level and managed accordingly. For intra-group transfers of personal data, the Novartis Group has adopted Binding Corporate Rules, a system of principles, rules and tools, provided by European law, in an effort to ensure effective levels of data protection relating to transfers of personal data outside the EEA and Switzerland. The Novartis Binding Corporate Rules are published on <https://www.novartis.com/our-company/corporate-responsibility/doing-business-responsibly/ethics-compliance/data-privacy>.

Where required, the transfer of data to a third country (outside the EU/EEA) was approved by the data controller's country data protection authority (the Bulgarian Data Protection Commission).

## **6.2 Consent Collection**

Consent for the publication of the ToVs was obtained and documented as such before disclosing the data on an individual HCP/HCO level where applicable<sup>3</sup>. Consent management procedures were conducted in alignment with the applicable data protection

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<sup>3</sup> New EU Regulation (GDPR) lays down rules relating to the protection of natural persons with regard to the processing of personal data.

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laws (including EU General Data Protection Regulation and the Bulgarian the Data Protection Act).

Consent was obtained either on Recipient level for all ToVs during a given period of time not shorter than one full year or on spend level for each interaction or single ToVs.

Alcon Bulgaria does not accept partial consent or split disclosure.

In case consent was either not given by the Recipient or not documented sufficiently to prove the existence of consent, ToVs are disclosed on aggregate level only.

In the event of death of an HCP by the time of disclosure (by the publication date) the ToV is reported in aggregate.

HCP has a right to withdraw the consent. Consent withdrawals, if any, shall be processed in accordance with the applicable data protection laws.

## **7. Financial Aspects**

This chapter focuses on the financial aspects related to recognition methodology and business decisions associated with the collection and disclosure of the ToVs information.

Alcon Bulgaria complies with the Alcon's accounting principles and the financial disclosure methodology - pursuant to the.

Alcon Bulgaria decided to apply the following rules for ToVs payment dates based on type of ToVs: direct ToVs are disclosed based on the date the financial document is entered (booked) in the accounting system. Indirect ToVs related to events such as congresses for which the dates of (in kind) expenses differ from the date(s) the event took place, are disclosed using the date the financial document is entered (booked) in the accounting system.

Alcon Bulgaria discloses ToVs net amount only. If VAT cannot accurately be excluded, the full ToV amount is disclosed. Where income tax or equivalent is withheld by Alcon Bulgaria on amounts earned by the HCP then the ToV will include these amounts.

Currency treatment – foreign currency ToVs will be converted using actual exchange rates in agreement with the accounting policy of Alcon Bulgaria ToVs will be disclosed in the local currency of the country where the disclosing entity is located. For direct and indirect ToVs, the foreign currency is converted to the local currency of the disclosing entity based on the transaction date. For cross-border ToVs, the foreign currency is converted to the local currency of the disclosing entity based on the average rate for the month in which the ToV occurred, using the Novartis Treasury rates.

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In case of cross-border ToVs as defined in chapter 5.2, direct ToVs will be recognized when the payment has been cleared via the banking system and indirect ToVs will be related to the end date of the event.

In case of multi-year contracts, ToVs are recognized based on the date the payment has been cleared via the banking system.

## 8. Published Data

Alcon Bulgaria applies the EFPIA definition of “Form of Disclosure” as outlined in EFPIA Disclosure Code Article 2 - pursuant to Article 13 and Exhibit № 1 to the ARPharM Disclosure Code.

Disclosures are made on annual basis within 6 months after the end of the relevant calendar year.

Publication is made on the following disclosure platform: <https://www.novartis.bg/prozrachnost>. Links to this platform will be published at [www.novartis.com](http://www.novartis.com) and <http://www.transparencybg.org>. The above platform fulfills the recommendation of the EFPIA Disclosure Code as being a platform accessible in the country where the Recipient has the primary practice and following the local laws or regulations of the country where the Recipient has their practice.

Updates of published data are conducted on annual basis after disclosure submission or when required as per the applicable law or ARPharM Disclosure Code, for example, in case of consent withdrawal.

This data will remain published in public domain years for 3 years following the disclosure (disclosure has to be done not later than 6 months as of the end of the year of payment) and shall be stored by Alcon Bulgaria for a period of a minimum of 5 years as of the end of the payment year.

Violation of the ARPharM Disclosure Code shall mean any act or omission by Alcon Bulgaria to disclose the transfer of value by which the company has violated the provisions of the ARPharM Disclosure Code.

The competent body to deal with complaints for violations of the ARPharM Disclosure Code is the Ethics Committee with the association.

Complaints and reports of violations of the ARPharM Disclosure Code may be submitted to the Ethics Committee of ARPharM in accordance of the requirements under Article 27 of the ARPharM Disclosure Code or to EFPIA. Complaints submitted to EFPIA shall be forwarded for consideration by the Ethics Committee of ARPharM. Complaints are processed by the Ethics Committee in accordance with Article 28 of the ARPharM

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Disclosure Code. The decisions of the Ethics Commission may be appealed as per Article 29 of the ARPharM Disclosure Code.

When a violation of the ARPharM Disclosure Code is established, the Ethics Commission may impose a monetary sanction between BGN 2000 BGN and BGN 7000, depending on the nature and seriousness of the violation. The decision of the Ethics Commission must be disclosed to the parent company and other companies that have signed the ARPharM Disclosure Code. For repeated violations (two or more violations within a calendar year) the Ethics Commission may impose a sanction equal the double amount of the maximum permissible sanction, disclose its decision to the parent company and other companies that have signed the ARPharM Disclosure Code, and shall publish the decision on its web page, stating the name of the company that violated the ARPharM Disclosure Code and details of the case.

The decisions of the Ethics Commission or extracts thereof shall be published on the website of ARPharM. Depending on the nature and seriousness of the violation, the Ethics Commission shall consider whether the published decision contains the name of the company that violated the ARPharM Disclosure Code and details of the case.

Also, Alcon Bulgaria applies the MedTech definition of “Form of Disclosure” as outlined in MedTech Disclosure Code Part 2, Chapter 3.

Disclosures shall be made on the EthicalMedTech website ([www.ethimedicalmedtech.org](http://www.ethimedicalmedtech.org)) unless the Member Company is already bound by national laws, regulations or professional codes as regulated in Section 1.2 “Applicability of these Disclosure Guidelines”. Member Companies will remain liable for the accuracy of the disclosed data. For the avoidance of doubt, MedTech Europe shall not be held liable for:

- maintaining, correcting, deleting the published data nor
- for the storage of data after the three years period of disclosure in the public domain.

Member Companies shall be able to modify, delete or in any way alter their disclosures at any time before or after the time of publication. The information disclosed shall remain in the public domain for 3 years after the time such information is first published.

## 9. Acronyms and Abbreviations

This chapter includes a list of acronyms, abbreviations and definitions for documentation purpose, based on the Schedule 1 of the EFPIA Disclosure Code and ManTech Disclosure Code whenever possible:

- **Conference Vetting System (CVS) (MedTech):** means the centralised decision-making process which reviews the compliance of Third Party Organised Educational Events with the Code and which is managed independently of MedTech Europe under

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the supervision of the MedTech Europe Compliance Panel. For more information see: <http://www.ethicalmedtech.eu>.

- **Contract Research Organization (CRO):** an organization that provides support to the pharmaceutical, biotechnology, and medical device industries in the form of research services outsourced on a contract basis.
- **Educational Grants (MedTech):** means provision of funding, Member Company or third party products or other in kind support to a Healthcare Organisation by or on behalf of a Member Company on a restricted basis for use solely for the support and the advancement of genuine medical education of Healthcare Professionals, patients and/or the public on clinical, scientific and/or healthcare topics relevant to the therapeutic areas in which the Member Company is interested and/or involved.
- **Healthcare Professional (HCP):**
  - **EFPIA:** Any natural person that is a member of the medical, dental, pharmacy or nursing professions or any other person who, in the course of his or her professional activities, may prescribe, purchase, supply, recommend or administer a medicinal product and whose primary practice, principal professional address or place of incorporation is in Europe. For the avoidance of doubt, the definition of HCP includes: (i) any official or employee of a government agency or other organization (whether in the public or private sector) that may prescribe, purchase, supply or administer medicinal products and (ii) any employee of a Member Company whose primary occupation is that of a practicing HCP, but excludes (a) all other employees of a Member Company and (b) a wholesaler or distributor of medicinal products.
  - **MedTech:** means any individual (with a clinical or non-clinical role; whether a government official, or employee or representative of a government agency or other public or private sector organisation; including but not limited to, physicians, nurses, technicians, laboratory scientists, researchers, research co-coordinators or procurement professionals) that in the course of their professional activities may directly or indirectly purchase, lease, recommend, administer, use, supply, procure or determine the purchase or lease of, or who may prescribe medical technologies or related services.
- **Healthcare Organization (HCO):**
  - **EFPIA:** Any legal person (i) that is a healthcare, medical or scientific association or organization (irrespective of the legal or organizational form) such as a hospital, clinic, foundation, university or other teaching institution or learned society (except for patient organizations within the scope of the EFPIA PO Code) whose business address, place of incorporation or primary place of operation is in Europe or (ii) through which one or more HCP provide services.

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- **MedTech:** means any legal entity or body (irrespective of its legal or organisational form) that is a -healthcare, medical or scientific association or organisation which may have a direct or indirect influence on the prescription, - recommendation, purchase, order, supply, utilisation, sale or lease of medical technologies or related services such as a hospital or group purchasing organisation, clinic, laboratory, pharmacy, research institution, foundation, university or other teaching –institution or learned or professional society (except for patient organisations); or through which one or more Healthcare – Professionals provide services.
  - **Member Associations:**
    - **EFPIA:** Collectively, the national Member Associations or their constituent members, as the context may require, and bound by the EFPIA codes of practice, including the EFPIA HCP Code, the EFPIA Patient Organization Code and the EFPIA HCP/HCO Disclosure Code.
    - **MedTech :** means all full and associate national association members of Eucomed and/or EDMA (or as applicable MedTech Europe) (“**Member Associations**”), as defined in the respective Eucomed, EDMA or MedTech Europe statutes, as applicable and as amended from time to time.
  - **Member Companies:**
    - **EFPIA:** Collectively, “corporate members” (as defined in the HCP Code) of EFPIA, their respective parent companies, if different, subsidiary companies (irrespective of whether a subsidiary is a company or such other form of enterprise or organization) and any companies affiliated with corporate members or their subsidiaries. Separate entities belonging to the same multinational company – which could be the parent company (e.g. the headquarters, principal office, or controlling company of a commercial enterprise), subsidiary company or any other form of enterprise or organization – shall be deemed to constitute a single company, and is as such committed to compliance with the EFPIA Codes.
  - **Professional Conference Organizer (PCO):** a company which specializes in the organization and management of congresses, conferences, seminars and similar events.
  - **Recipient:** Any HCP or HCO/PCO as applicable, in each case, whose primary practice, principal professional address or place of incorporation is in a country whose association is a member of EFPIA and/or MedTech.
  - **Scholarships and Fellowships (MedTech):** means Educational Grants provided to a Healthcare Organisation by or on behalf of a Member Company to support fellowships or scholarships offered by the Healthcare Organisation. Scholarships in this context

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means an Educational Grant provided to support a medical school undergraduate whereas a fellowship is a period of intensive training for post-graduate physicians in a chosen clinical sub-specialty (e.g. medical training after a residency). “Scholars” and “Fellows” shall be understood accordingly.

- **Third Party Organised Educational Events (MedTech):** means activities of any type that are planned, budgeted, managed and executed in whole or in part by or on behalf of a person or entity other than a Member Company to fulfil Healthcare Professional medical educational needs.
- **Third Party Organised Educational Conferences (MedTech) :** means a type of Third Party Organised Educational Event that is a genuine, independent, educational, scientific, or policy-making conference organised to promote scientific knowledge, medical advancement and/or the delivery of effective healthcare and are consistent with relevant guidelines established by professional societies or organisations for such educational meetings. These typically include conferences organised by national, regional, or specialty medical associations/societies, hospitals, Professional Conference Organisers (PCOs), patients organisations or accredited -continuing medical education providers.
- **Third Party Organised Procedure Training (MedTech):** means a type of Third Party Organised Educational Event that is primarily intended to provide Healthcare Professionals with information and training on the safe and effective performance of one or more clinical procedures in circumstances where the information and training concern:
  - Specific therapeutic, diagnostic or rehabilitative procedures, namely clinical courses of action, methods or techniques (rather than the use of medical technologies); and
  - Practical demonstrations and/or training for HCPs, where the majority of the training programme is delivered in a clinical environment.Proctorships and preceptorships are not considered to constitute Third Party Organised Procedure Training.
- **Research and Development ToVs:** ToVs to HCPs or HCOs related to the planning or conduct of (i) non-clinical studies (as defined in OECD Principles on Good Laboratory Practice); (ii) clinical trials (as defined in Directive 2001/20/EC); or (iii) non-interventional studies that are prospective in nature and that involve the collection of patient data from or on behalf of individual, or groups of, HCPs specifically for the study (Section 15.01 of the EFPIA HCP Code).
- **Transfers of Value (ToVs):**
  - **EFPIA:** Direct and indirect transfers of value, whether payments, in kind or otherwise, made, whether for promotional purposes or otherwise, in connection with the development and sale of prescription-only Medicinal Productsexclusively for human use. Direct transfers of value are those made

directly by a Member Company for the benefit of a Recipient. Indirect transfers of value are those made on behalf of a Member Company for the benefit of a Recipient, or transfers of value made through an intermediate and where the Member Company knows or can identify the HCP/HCO that benefit from the Transfer of Value.

- **MedTech:** covers provision of funds for the support and the advancement of genuine medical education of HCP, patients and/or the public on clinical, scientific and/or health care topics relevant to the therapeutic areas as Educational Grants.
- **EFPIA:** The European Federation of Pharmaceutical Industries and Associations
- **ARPharm:** The Association of the Research-based Pharmaceutical Manufacturers in Bulgaria
- **MedTech:** Medtech Europe- the European trade association representing the medical technology industries, from diagnosis to cure. It represents Diagnostics and Medical Devices manufacturers operating in Europe.

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